APPENDIX

United States Court of Appeals,
Eighth Circuit.

Carol Jean BROOKS, Plaintiff-Appellant;
ST. LUKE'S HOSPITAL, Intervenor Below,

v.

HOWMEDICA, INC., a Delaware Corporation, Division of Pfizer Hospital Products Group, Inc.; Pfizer, Inc.; Howmedica International, Ltd., Defendants-Appellees.

PRODUCT LIABILITY ADVISORY COUNCIL, INC., Amicus on Behalf of Appellees.

No. 00-1188.

Submitted: July 10, 2001.
Filed: Dec. 11, 2001.

Appeal from the United States District Court
for the District of Minnesota.

Before WOLLMAN, Chief Judge, HEANEY, McMILLIAN, BOWMAN, LOKEN, HANSEN, MORRIS SHEPPARD ARNOLD, MURPHY, and BYE, Circuit Judges.

MURPHY, Circuit J.

Carol Jean Brooks brought this action against the manufacturer of Simplex bone cement claiming damages for injury resulting from its failure to give adequate warnings about product dangers. The case was dismissed on summary judg-

ment after the district court[1] concluded that her claim was preempted by federal law, § 360k of the 1976 Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. A panel of this court reversed with one judge dissenting, *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir. 2001), a petition for rehearing en banc was granted, and the panel opinion was vacated. After examining the record and considering *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), we affirm the judgment of the district court.

I.

Carol Jean Brooks is a licensed practical nurse whose work as a surgical technician included mixing bone cement. Bone cement is used to bond with a bone or prosthesis in orthopedic surgeries, including joint replacements. Brooks began mixing bone cement during 1978 while she worked at St. Mary's Hospital in Duluth, Minnesota, but her principal exposure occurred after she moved to St. Luke's Hospital in Duluth in 1982. At St. Luke's she initially participated in a variety of surgeries, but in 1983 she began to assist almost exclusively in orthopedic surgeries, mixing bone cement or being present during its preparation approximately four times a week. By 1992 she was mixing bone cement or was close to the mixing process during approximately ten surgeries a week. Although Brooks is unable to identify the brand of bone cement used at St. Mary's, it is undisputed that St. Luke's used Simplex P Radiopaque bone cement (Simplex), which was manufactured and marketed by appellees (collectively Howmedica).[2]

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[1] The Honorable Michael J. Davis, United States District Judge for the District of Minnesota.

[2] At the time this action was commenced, defendants Howmedica Inc. and Howmedica International, Ltd. were wholly owned subsidiaries of defendant Pfizer, Inc. The record does not make clear which corporate entity was responsible for manufacturing or sell-

Brooks began to cough at some time in 1989 or 1990. She went to see a doctor about it in 1991 when she was told she had asthma. An occupational health physician at St. Luke's Hospital also investigated possible causes for her cough, reviewed Howmedica's Material Safety Data Sheet, and talked with a Howmedica chemist, but that investigation did not link her cough to Simplex. St. Luke's restricted her exposure to a number of chemicals after an acute asthma attack in 1992; the restriction included methyl methacrylate which is an ingredient in Simplex. Brooks was later diagnosed to have occupational asthma caused by exposure to methyl methacrylate. Brooks has been unable to work since 1995.

Brooks brought a failure to warn claim against Howmedica, alleging that it had not provided "adequate warnings and instructions" for Simplex use and that as a result, she had contracted "severe asthma and associated respiratory complications." Howmedica asserted federal preemption and also denied that the Simplex label contained inadequate warnings and instructions or that it proximately caused Brooks' injury. St. Luke's Hospital intervened, seeking compensation from Howmedica for what it had paid Brooks in workers compensation benefits, costs, interest, disbursements, and attorney fees, but it is not involved in this appeal.

II.

Starting in the early 1970's Howmedica began to market bone cement in the United States under the trade mark Simplex. Bone cement is sold in two separately packaged components: methyl methacrylate monomer which is a colorless liquid and a powder mixture containing polymethyl methacrylate, methyl methacrylate styrene copolymer, and barium sulfate. The liquid and powder are mixed together in

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ing Simplex during the time Brooks was injured, but none of the appellees has challenged its status as a defendant.

the operating room to form a pliable mass that later hardens into a cement like consistency. The mixing process releases vapors containing methyl methacrylate, which is classified as a hazardous chemical by the Occupational Safety and Health Administration.

It is undisputed that Simplex has been heavily regulated by the FDA since it entered the market when it was treated as a drug subject to the Federal Food, Drug, and Cosmetic Act of 1938 (1938 Act). The 1938 Act required Howmedica to submit a New Drug Application (NDA) before it could sell Simplex,[3] see 21 U.S.C. § 355, and the NDA is a rigorous process. The NDA process required Howmedica to disclose details of animal studies, manufacturing and quality control procedures, the identification of possible side effects, results of clinical trials, summaries of surgical cases and post operative complications, long term toxicity, and carcinogenicity studies. The process also produced reports from the investigational use of Simplex by sixty seven physicians in 1,408 hip replacements which involved 2,800 preparations of the product. All these submissions were then studied and reviewed by a panel of FDA experts. Under the 1938 Act, Simplex could not be marketed without approval by the Secretary of Health and Human Services. See 21 U.S.C. § 360(c) (premarket approval process).

The NDA included review by the FDA of the proposed design and content for all Simplex labels, including labels for a vial, a pouch, two internal boxes, an outer box, and a package insert. Howmedica employees met with members of the FDA on several occasions to discuss its application, including the product labels. The FDA reviewed every word that

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[3] Howmedica developed and submitted NDAs for two types of Simplex. The only difference between the two is that one type was detectable on x-ray and the other was not. The approval process was identical for both types, and neither side in this case differentiates between the two.

appeared on Simplex labels, and the FDA drafted the language that was used in the package insert. That package insert included the following warning:

> As the liquid monomer is highly volatile and flammable, the operative room should be provided with adequate air circulation. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

The vial containing the liquid component and the box with the powder both referred the user to the package insert for information regarding dosage and administration.

Simplex was approved by the FDA for use in total hip replacement surgeries in 1971. The FDA wrote "[w]e have completed the review of this application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved."

These review requirements were affected by the 1976 Medical Device Amendments (MDA) to the 1938 Act. The MDA created three classes of medical devices, categorized by the risk to the public and the degree of regulation required. Class I devices present no unreasonable risk of illness or injury and are subject only to "general controls." 21 U.S.C. § 360c(a)(1)(A). Class II devices present greater risk than those in Class I, and they must comply with federal performance regulations called "special controls" but may be marketed without advance approval. *Id.* at § 360c(a)(1)(B). Class III devices carry "a potential unreasonable risk of illness or injury," or are used for "supporting or sustaining human life," or are seen to be "of substantial importance in preventing impairment of human health." *Id.* at § 360c(a)(1)(C). Class III devices are highly regulated and must receive pre-

market approval (PMA) from the FDA before they may be sold. *Id.* at § 360e(a).[4]

Devices such as Simplex, which had been treated as drugs prior to the amendments to the 1938 Act, were automatically reclassified by the MDA as Class III medical devices.[5] See 21 U.S.C. § 360j(l)(1). The statute provided that these devices were deemed to have PMA approval if they had gone through the NDA approval process. *Id.* at § 360j(l)(3)(A). Beginning in 1976 Simplex was accordingly treated as a Class III medical device with PMA approval.

Under both the 1938 Act and the MDA, the FDA has continuing authority and responsibility to control the content of any information or warnings Howmedica provides Simplex users. Howmedica was required to provide the FDA with regular reports of any new information learned about Simplex. See 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80, 314.81, 814.84 (2000). The company was not permitted to make any changes to the product label affecting the safety or effectiveness of the device without submitting a supplemental PMA, but it could temporarily "add or strengthen" warnings during the time the FDA had any supplement under consideration. 21 C.F.R. § 814.39(a), (d) (2000).

Howmedica learned that some individuals exposed to Simplex had developed contact dermatitis, and in 1973 it requested permission from the FDA to insert the following language into its warnings: "The liquid component is a powerful lipid solvent, and may also act as a sensitizer in certain individuals." After its consideration of the request, the FDA de-

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[4] There are certain exemptions to the PMA requirement which do not apply to Simplex but are discussed in *Kemp* v. *Medtronic*, 231 F.3d 216, 221-22 (6th Cir. 2000).

[5] The FDA later reclassified bone cement from a Class III device to Class II, but that was at a time after the period during which Brooks was exposed to Simplex.

cided to direct Howmedica to revise its package insert to include this additional language:

> The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or be absorbed by the body.

In 1975, the FDA required bone cement manufacturers to participate in a review of the inhalation toxicity of methyl methacrylate vapors, and the Simplex warnings were reexamined. After a number of discussions, the FDA required Simplex to modify the package insert warnings concerning vapor inhalation as follows:

> As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to eliminate the maximum amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

The FDA also directed Howmedica to send a "Dear Doctor" letter to Simplex users to warn about inhalation hazards associated with methyl methacrylate. Howmedica told the FDA it believed the letter was unnecessary because studies had shown that the concentration of methyl methacrylate vapors in operating rooms was within accepted limits, but the FDA insisted on compliance with its directive. Howmedica and the FDA then worked together to draft the letter, which directed attention to methyl methacrylate vapor inhalation studies and to the package insert warning. It also recom-

mended that hospital facilities be inspected for adequate ventilation. The final paragraph of the letter warned:

> In some sensitive individuals, exposure to MMA can cause dermatitis and other allergenic responses. If any of your operating room personnel develop such responses when using Simplex®, both prudence and good medical practice would suggest that they avoid all procedures involving use of Simplex®.

Howmedica sought to expand the uses of Simplex, and in March 1976 the FDA approved its request from the previous year to use the product in fixing pathological fractures. The FDA approved the request with the condition that Howmedica send the "Dear Doctor" letter to members of the American Academy of Orthopaedic Surgeons and to all hospital administrators and operating room supervisors at hospitals and clinics which had recently purchased Simplex. In July, Howmedica submitted a supplemental NDA to seek approval of Simplex use in elbow, wrist, ankle, shoulder, and finger joint replacement surgery. During this application process, the FDA again reviewed Simplex labels and required specific changes be made to reflect these uses. After Howmedica had made the required labeling changes, the FDA approved the application.

In 1986, Howmedica received information that soft contact lenses could be damaged by methyl methacrylate vapors and requested that additional warnings be added to Simplex labels. The FDA approved the addition of the following warning:

> It has been recommended by manufacturers of soft contact lenses that such lenses should be removed 'in the presence of noxious and irritating vapors.' Since soft contact lenses are quite permeable, they should not be worn in an operating room where methyl methacrylate is being mixed.

This addition was the final adjustment made to the Simplex warning related to occupational use during the period when Carol Brooks was exposed to the product.

III.

After discovery was complete in the district court, Howmedica moved for summary judgment. It argued that Brooks' failure to warn claim was preempted by the MDA because she sought to impose a requirement on Simplex that was different from, or in addition to, federal requirements developed through the NDA process. It also argued that any inadequacy in Simplex warnings was not the proximate cause of Brooks' injury because she admitted she had never read the product labels or package insert. Brooks argued that her claim was not preempted because the duty to warn is a general obligation applicable to all devices, and approval by the PMA or NDA does not impose specific federal requirements with preemptive effect. She also asserted at this time that Howmedica had failed to comply with general FDA labeling regulations although she had not pled such a claim in her complaint.

The district court granted Howmedica's motion and dismissed the case. After a comprehensive discussion of the relevant case law, the court concluded that even if Brooks could show that her injury had been caused by Howmedica's failure to provide her with adequate warnings and directions for use, her failure to warn claim was preempted by federal law and that she had not submitted sufficient support for any claim that Howmedica failed to comply with FDA rules or regulations.

Brooks appealed, arguing that her general common law duty to warn claim was not preempted and that the NDA and PMA are not specific federal requirements with preemptive force. She also argued that Howmedica's alleged breach of its duty under common law amounted to a violation of general FDA labeling requirements. Howmedica responded that

Simplex is deemed under the MDA to have PMA approval and that the PMA has been recognized by this court to be a federal requirement with preemptive effect, citing *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). It argued that Brooks' claim was a state requirement different from, or in addition to, the federal requirement and therefore preempted under § 360k of the MDA. Howmedica also argued that Brooks had provided no evidence that it had violated any FDA rules or regulations. Both sides contended that the Supreme Court's decision in *Medtronic* v. *Lohr*, 518 U.S. 470 (1996), favored their respective positions.

A panel of this court reversed the dismissal of the failure to warn claim, with one judge dissenting. *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir. 2001). The majority interpreted Lohr to permit the claim to go forward, holding that the claim would not result in any actual conflict between state common law and federal requirements and was therefore not preempted. *Id.* at 964-66. The dissent pointed out that the device at issue in Lohr had been approved through a much less rigorous process than the PMA and the NDA review of Simplex, and that during the regulatory process for Simplex the FDA had considered a particular federal requirement, had concluded how competing considerations regarding that requirement should be resolved, and had imposed a specific mandate on Howmedica to that end. *Id.* at 967. The panel treated Brooks' allegation that Howmedica had not complied with FDA regulations as a common law negligence per se claim and affirmed its dismissal. *Id.* at 966-67.

Howmedica's petition for rehearing en banc was granted, and the panel opinion was vacated. The parties submitted additional briefs, and the Product Liability Advisory Council, Inc. was given permission to submit an amicus brief.[6] At

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[6] In its brief the Product Liability Advisory Council asserts that Brooks' claim is preempted under the MDA. It argues that neither

oral argument, the parties advanced substantially the same points they had made earlier, but Brooks put increased emphasis on her contention that the link between methyl methacrylate and occupational asthma had not been made until 1985. She asserts that the product warning was not changed in response to the publication in 1985 of two articles linking methyl methacrylate and occupational asthma and that it is not clear that the FDA ever considered such a risk. Howmedica responds that the FDA decided on the wording of the warnings for the Simplex package insert with full awareness of the respiratory risks.

IV.

A grant of summary judgment is reviewed de novo. *United States* v. *Scherping*, 187 F.3d 796, 800 (8th Cir. 1999). Summary judgment is proper when there is no genuine issue of material fact and the moving party would be entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322-23 (1986). Brooks contends that her state claim for failure to warn is not preempted under the MDA, and she also advances an argument that she has a state claim of inadequate labeling which "parallels" federal labeling requirements. Howmedica responds that the district court correctly dismissed the claims on summary judgment.

A.

State law which conflicts with federal law is preempted under the Supremacy Clause of the Constitution. U.S. Const., Art. VI, cl. 2. Congressional intent to preempt state law can either be expressed in statutory language or implied in the structure and purpose of federal law. *Cipollone* v. *Liggett*

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state nor federal requirements need to be "device-specific" in order to warrant federal preemption and that permitting claims such as the one alleged by Brooks would cause "over-warning" injurious to the FDA's regulatory goals and to the public health.

Group, Inc., 505 U.S. 504, 516 (1992).[7] At the time Carol Brooks was exposed to Simplex, the product was regulated as a Class III device under the MDA, which contains an express preemption provision, codified at 21 U.S.C. § 360k:

> (a) [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
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> > (1) which is different from, or in addition to, any requirements applicable under this [Act] to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].

21 U.S.C. § 360k.

At first glance the preemption issue presented here under § 360k might seem quite simple since the state law result sought by Brooks relates to safety and would impose different or additional requirements on the product warning for Simplex. That the issue is not so simple is evidenced by *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470 (1996), a case in which a sharply divided Supreme Court interpreted § 360k.

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[7] Howmedica asserts that Brooks' failure to warn claim is expressly preempted by § 360k, but on appeal it has also argued in the alternative that her claim is impliedly preempted under federal law. Because we find express preemption, we do not address any potential issue of implied preemption. We notice parenthetically, however, that the Supreme Court recently held that state law claims of fraud on the FDA are impliedly preempted under federal law, "express[ing] no view" on whether such claims are subject to express preemption under § 360k. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 348 n.2 (2001).

Lohr involved claims relating to the design, manufacture, and labeling of a pacemaker, including claims for common law failure to warn and violation of FDA regulations. *Id.* at 481, 495. The manufacturer unsuccessfully attempted to persuade a majority of the Court that Lohr's failure to warn claim was barred by the MDA preemption provision. The Court split, with Justice Breyer the swing vote as he joined first one group of justices, then the other. Justice Stevens, writing for a four justice plurality, stated that § 360k would rarely, if ever, preempt state common law claims. *Id.* at 502. Justice O'Connor on behalf of four dissenting justices disagreed, believing that § 360k preempts any state requirement — including a common law duty — that is "different from, or in addition to" a federal requirement. *Id.* at 514. Justice Breyer agreed with Justice O'Connor that state common law claims can be subject to preemption under § 360k, *id.* at 503, but he joined Justice Stevens and the plurality in ruling on *Lohr's* claim for failure to warn.

In a part of the opinion written by Justice Stevens and joined by Justice Breyer, the *Lohr* Court examined the regulations promulgated by the FDA which contain the agency's interpretation of § 360k:

> (d) State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements * * *.
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> (1) [§ 360k] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices * * * or to unfair trade

> practices in which the requirements are not limited to devices.
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> * * *
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> (6)(ii) Generally, [§ 360k] does not preempt a State or local requirement prohibiting the manufacture of * * * misbranded devices [unless] such a prohibition has the effect of establishing a substantive requirement for a specific device, *e.g.*, a specific labeling requirement, [that is] different from, or in addition to, a Federal requirement established under the act * * *.

21 C.F.R. § 808.1(d) (2000). These regulations attempt to clarify the intended meaning of the statutory language, and the *Lohr* Court said it was "substantially informed" by them. 518 U.S. at 495.

Drawing on the statute and the regulations, the Stevens majority in *Lohr* described a series of requirements necessary for a finding of preemption under the MDA. State requirements are preempted only if they relate to "the safety or effectiveness of the device" or to another matter included in a requirement applicable to the device. *Id.* at 500. State requirements must be "with respect to" medical devices, and state requirements of "general applicability" are subject to preemption only if they have the effect of establishing a substantive requirement for a specific device. *Id.* Federal requirements must also be "applicable to the device" at issue; that is, they must be "specific counterpart regulations" or specific to the particular device. *Id.* State law will be preempted under the MDA when "a particular state requirement threatens to interfere with a specific federal interest." *Id.*

The Court concluded that Lohr's failure to warn claim was too general to require preemption. *Id.* at 502. Although the duty to inform users of potential product dangers applies to all manufacturers, this general duty was "not specifically

developed 'with respect to' medical devices." *Id.* at 501. Medtronic's duty to warn in respect to the pacemaker was not the kind of "requirement[ ] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Id.*

If some of the language in *Lohr* were read without careful consideration of the separate opinions, it might imply that no state tort claim could ever be preempted since each is based on broadly applicable common law duties. Such a reading would directly contradict the view of a separate majority of the Court, however, for five justices concurred in Justice O'Connor's statement that § 360k "clearly preempts any state common-law action that would impose a requirement different from, or in addition to" a specific federal requirement. *Id.* at 511. See also *id.* at 503 (Breyer, J., concurring).

The crux of the disagreement in *Lohr* between the Stevens majority and the dissenters is the meaning to be given to the statutory phrase "a requirement different from, or in addition to." *Lohr* instructs that state requirements — including common law duties — are preempted to the extent that they interfere with specific federal requirements. The state and federal restrictions must be "carefully compar[ed]" to ascertain whether there is interference between them — that being the "overarching concern" of the test articulated by Justice Stevens and joined in by Justice Breyer. *Id.* at 500. A state claim will be preempted in circumstances where "a particular state requirement threatens to interfere with a specific federal interest." *Id.* In his concurring opinion Justice Breyer phrased the issue as whether an "actual conflict" exists between the state and federal requirements, *id.* at 508,[8] and that opinion

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[8] In his opinion Justice Breyer cited earlier Supreme Court cases describing "conflict" preemption. 518 U.S. at 507. Among the cases he cited was *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992), which explained that a state requirement is preempted if it actually conflicts with a federal requirement, either

deserves close attention since his vote created the majority. The key question before the court is whether the specific state requirement Brooks wishes to impose on Simplex would interfere with a specific federal requirement, but the question may also be phrased as whether the specific state and federal requirements conflict.

In *Lohr*, the plaintiff's failure to warn claim did not conflict with the federal requirements imposed on the Medtronic pacemaker. The product had received FDA approval through a system intended to allow rapid introduction of improvements to existing devices. *Id.* at 478. Under the § 510(k) process[9] involved in *Lohr*, a device can be sold without PMA approval if it is "substantially equivalent" to one already on the market. See 21 U.S.C. § 360e(b)(1)(B); 21 C.F.R. 814.1(c)(1) (2000). A substantially equivalent device is examined in the § 510(k) process only for similarities with existing devices; safety and effectiveness are not the focus. *Lohr*, 518 U.S. at 493. Section 510(k) approval is a mere grant to market; it imposes no "requirements" of its own. *Id.* at 493-94. The pacemaker there was subject to a federal regulation requiring Medtronic to provide a label indicating "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (2000). This requirement applied to all manufacturers in the industry and reflected generic concerns about device regulation. It did not require the FDA to be involved in the drafting or approval of the pacemaker's product label. The requirement was not specific, and a common law claim would not "impede the ability of federal regulators to implement and enforce" it. 518 U.S. at 501.

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because compliance with both is impossible or because the state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* at 98 (1992) (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)).

[9] The type of process established under § 510(k) of the MDA as enacted in 1976.

The facts in the case before the court are very different from those in *Lohr*. The FDA drafted or approved every word of the Simplex label, and any changes were subject to close FDA scrutiny. PMA review typically requires 1,200 hours of rigorous testing for device safety. In contrast, § 510(k) review focuses on "substantial equivalence" and is completed in an average of twenty hours. *Id.* at 479. The two processes are "by no means comparable." *Lohr*, 518 U.S. at 478.

B.

Our court considered the preemptive effect of the MDA in a decision predating *Lohr*, *Martello* v. *Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994). In *Martello*, we held that the PMA is a specific federal requirement within the meaning of § 360k which preempts state court claims involving safety "when the claims would impose additional requirements in areas [it has] regulated." *Id.* at 1169. Under *Lohr* this holding requires some modification because common law claims are only preempted to the extent that they threaten to interfere with specific federal requirements. 518 U.S. at 501-02.

Most courts of appeal have interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements. See, *e.g.*, *Martin* v. *Medtronic Inc.*, 254 F.3d 573, 582 (5th Cir. 2001); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 230 (6th Cir. 2000); *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 913-14 (7th Cir. 1997); *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). But see *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997) (common law failure to warn claim is not subject to preemption under the MDA). *Martin*, *Kemp*, and *Mitchell* all considered failure to warn claims involving products which had had a full PMA like that undergone by Simplex. The Fifth Circuit in *Martin* concluded that a general duty of care under state law is preempted if "the elements needed to prove [its] violation" are specific and

"therefore threaten specific federal requirements." 254 F.3d at 582. Because the design of the Martin product label had been approved by the FDA through the PMA process, a failure to warn claim would impose state requirements that would conflict with specific federal requirements and it was therefore preempted. *Id.* at 584-85. Similarly, the Sixth Circuit in *Kemp* held that a common law claim is preempted if it would add "different" or "additional" elements to specific federal requirements approved through the PMA. 231 F.3d at 236. The Seventh Circuit also concluded in *Mitchell* that when a manufacturer has adhered to the PMA process, a common law claim of mislabeling is preempted because it would impose "different" or "additional" requirements. 126 F.3d at 913-14. *Cf. Papike*, 107 F.3d at 742 (failure to warn claim preempted by FDA labeling regulations regarding toxic shock syndrome).

Those circuit court decisions since *Lohr* which have not found preemption in failure to warn cases were faced with circumstances different from those in this case. In *Oja*, the Tenth Circuit held that a common law duty to warn is not a "substantive requirement" subject to preemption, but that case involved approval through an investigational device exemption, a considerably less rigorous process than the full PMA. 111 F.3d at 786-87, 789. In *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), a case in which the FDA had issued no statement or order of requirements beyond review and approval of the initial PMA, the Eleventh Circuit ruled that simple approval of the PMA application imposes no federal "requirements." *Id.* at 1375. The *Goodlin* court implied, however, that it would find preemption in a case involving an "ascertainable requirement in an express FDA" order or regulation. *Id.* (citing *Papike*, 107 F.3d at 740-41). That is what we have here, where the FDA has issued a series of specific mandates regarding the label for Simplex. Simplex has been subject to continuing and specific

FDA regulation, beyond its initial approval through the PMA process.

C.

The failure to warn claim asserted by Brooks would interfere or conflict with the specific federal requirements imposed during the regulation of Simplex. A jury finding of negligent failure to warn would be premised on the fact that the label for Simplex was not written in a particular way or did not contain certain information. This would be equivalent to a state regulation imposing specific label requirements. Justice Breyer illustrated this principle in his concurring opinion in *Lohr* when he pointed out that if a jury were to find negligence in the use of a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two inch wire, there would be federal preemption as surely as if a state regulation were to impose such a limitation. *Id.* at 504 (Breyer, J., concurring).[10]

The effect of a jury finding of negligent failure to warn would be that state law would require Howmedica to change the label and package insert for Simplex, but Howmedica may not unilaterally make such changes under federal law. A device may not be labeled in a manner inconsistent with any conditions specified in its PMA. 21 C.F.R. § 814.80 (2000). A manufacturer must submit a Supplemental PMA for any proposed labeling changes that affect the safety of the device. *Id.* at § 814.39(a). Brooks points out that the regulations permit manufacturers to make temporary changes in the in-

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[10] See also *Martin*, 254 F.3d at 582-83; *Kemp*, 231 F.3d at 237 (Moore, J., concurring). Also illustrative is the report of one of Brooks' experts (Frank Junghans), which proposed revisions to the label, safety sheet, and package insert for Simplex, including additional language and colorful pictographs. A jury might adopt any of his suggestions as a state requirement after a trial on a common law claim.

terest of safety, see *id.* at § 814.39(d), but such changes are valid only after the manufacturer has submitted a Supplemental PMA and only during the pendency of that application. *Id.* at § 814.39(a)(2), (d)(1). Once the Supplemental PMA has been approved, modified, or denied, the manufacturer must comply with the FDA's decision. *Id.* at § 814.80.

Brooks argues that limiting the warnings on a label would not seem to advance the FDA's purpose to ensure device safety. There are, however, a number of sound reasons why the FDA may prefer to limit warnings on product labels. Warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks. A label with many varied warnings may not deliver the desired information to users. Space on product labeling material is also a factor, and the most effective labels are those with large, bold warnings and a simple design. See generally Ctr. for Devices & Radiological Health, U.S. Dep't of Health & Human Servs., *Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers* 42 (2001), available at <www.fda.gov/cdrh/ohip/guidance/1128.pdf>. See also Richard M. Cooper, Drug Labeling and Products Liability: *The Role of the Food & Drug Administration*, 41 FOOD, DRUG & COSM. L.J. 233, 237-38 (1986). The FDA's enabling statute also reflects these concerns: warnings must be "prominent[ ]" and "conspicuous[ ]," as compared with other material on the label. 21 U.S.C. § 352(c).

The arguments advanced by Brooks ignore the need for national uniformity in product regulation, one of the explicit goals of the MDA. The legislative history indicates that this was the reason the preemption provision was included within the MDA. H.R. REP. NO. 853, 45 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened."). The state requirement in this case would come from a com-

mon law duty as applied by an individual jury. Trials of tort claims pose incentives to overwarn: "the visible monetary costs of additional warnings are typically quite low — a few pennies for a bit more paper and a little more ink." James A. Henderson & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 297 (1990). It would be difficult for a jury focused on a single case to take into account "the cumulative, systemic effects" of a series of verdicts. Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2175 (2000). In contrast, the FDA possesses a broader perspective. Regulation by the FDA allows the agency to craft labels that maximize safety and effectiveness.

Brooks also claims that an alleged link between methyl methacrylate and occupational asthma first became known in 1985, well after the original FDA approval of Simplex in 1971. She suggests that the FDA did not consider such a danger nor impose any warning requirement with respect to it. She bases this argument on the fact that two articles appeared in 1985 which describe case studies linking methyl methacrylate and occupational asthma and one claimed there had been no previous published report of the chemical's association with asthma. S. Lozewicz et al., *Occupational asthma due to methyl methacrylate and cyanoacrylates*, 40 THORAX 836, 836 (1985). Neither of the two experts put forward by Brooks nor the cited articles claimed, however, that the risk of respiratory irritation from methyl methacrylate had not been previously appreciated, and the product labeling for Simplex and the "Dear Doctor" letter are evidence to the contrary.[11]

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[11] There is evidence that even by 1998 a specific connection between methyl methacrylate and occupational asthma had not been conclusively established. See World Health Organization, et al., Concise International Chemical Assessment Document No. 4,

The record demonstrates that the FDA was aware of a possible link between methyl methacrylate and respiratory damage for several decades, and the agency required Howmedica to take specific steps in response. The label for Simplex incorporated the danger of sensitivity to vapors from the very beginning. When Simplex was introduced in 1971, the FDA drafted a package insert which warned that the liquid methyl methacrylate used in mixing is "highly volatile" and that the mixing process required both "adequate air circulation" and caution "to prevent excessive exposure to the concentrated vapors" which could produce "irritation of the respiratory tract." In 1973 Howmedica requested permission to add to the warning to indicate that the ingredients of the product could "act as a sensitizer," but the FDA decided on different wording, requiring a warning about "strict adherence to the mixing instructions" to "diminish the possibility of hypersensitivity reactions" and to prevent absorption of the product.

The FDA conducted an official review of the inhalation toxicity of methyl methacrylate vapors by operating room personnel in 1975, and it subsequently directed Howmedica to send a "Dear Doctor" letter to Simplex users drafted by both Howmedica and the FDA. The letter directed user attention to methyl methacrylate vapor inhalation studies and to the package insert warning and recommended that user facilities be inspected for adequate ventilation. The FDA also mandated changes in the package label. The new version read:

> As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation so as to eliminate the maximum

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Methyl Methacrylate 5 (1998) ("Although occupational asthma associated with methyl methacrylate has * * * been reported, there is no conclusive evidence that methyl methacrylate is a respiratory sensitizer.")

> amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver. (emphasis added)

In 1986, after receiving reports of damage to soft contact lenses, Howmedica requested, and the FDA approved, an additional warning for the Simplex package insert referring to the vapors created during the mixing process as "noxious and irritating."

The FDA was deeply involved in drafting and editing the warnings on the Simplex label and package label, beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it. Through its approval of the PMA application for Simplex and its continuing series of directives, the agency imposed specific federal requirements on Howmedica. The failure to warn claim Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives. Because these "particular state requirement[s] threaten[ ] to interfere with * * * specific federal interest[s]," *Lohr*, 518 U.S. at 500, Brooks' claim is preempted by the MDA.

D.

Brooks also argued in the district court that Simplex instructions were inadequate under federal law because FDA regulations require package labeling for prescription products to contain information about "any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c) (2000). Brocks claims that her common law claim contains requirements identical to those imposed under federal law and is therefore not preempted. Brooks is correct in her assertion that a claim of failure to comply with FDA regulations is not preempted by the MDA, *Lohr*, 518 U.S. at

495, since such a state claim imposes no requirement "different from, or in addition to" any federal requirement. *Id.* at 496-97. See also *id.* at 513 (O'Connor, J ., concurring in part and dissenting in part). Her assertion that she has put forward such a cause of action is a separate issue, however. The district court dismissed "any claim that Howmedica failed to comply with FDA rules or regulations" because it found no showing of noncompliance. The panel treated this claim as one for negligence per se unsupported in the record. Brooks asserts that her argument has been misunderstood and that she alleges a violation of state law that "parallels" similar requirements under federal law.

This unpled claim lacks both clarity and support, and we find no error in its dismissal. To the extent that Brooks attempts to distance herself from the categorization of this claim as one for negligence per se, the claim begins to sound very similar to the preempted failure to warn claim just discussed. *Cf. Papike*, 107 F.3d at 742-43 (denying a claim that general labeling regulations require warnings beyond those contained in specific FDA requirements). Under the type of theory Brooks advances the general duty of C.F.R. 801.109(c) could trump even the most specific FDA labeling directive and § 360k of the MDA could be completely circumvented. Moreover, Brooks has presented no evidence that Howmedica violated federal regulations or refused to add warnings drafted by the FDA, changed FDA-approved labels failed to meet regular reporting requirements, failed to report a known hazard to the FDA, or failed to comply with federal law in any other respect. We conclude that this claim was properly dismissed on summary judgment.

V.

Simplex package labeling was subject to meticulous and ongoing federal regulation from the product's approval in 1971 through the time of Brooks' exposure to it. The FDA imposed specific federal requirements on Simplex through

the PMA and NDA process. The specific state requirement Brooks seeks to establish by her common law claim would interfere with the specific federal requirements set for Simplex. Her claim is therefore preempted under § 360k of the MDA because it would impose a specific state requirement "different from, or in addition to" specific federal requirements. There is also no showing that Howmedica violated federal regulations. For these reasons, we affirm the judgment of the district court.

BYE, Circuit Judge, with whom HEANEY, Circuit Judge, joins, dissenting in part.

The majority stitches together a coherent, scholarly explication of § 360k preemption from the complicated opinions of the Supreme Court in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 495 (1996). I admire the majority's efforts. I also agree with its development of a three-step test, in which courts must discern the federal requirement imposed on a medical device manufacturer, then the state requirement imposed on that manufacturer, and finally compare the two to determine whether they present conflicting obligations. Though I agree with the standard expressed by the majority, I strongly disagree with its application of that standard to the facts of Carol Brooks's case and I respectfully dissent in that respect.

Following *Lohr*, we search for incompatibility between state laws (or putative state court judgments) and federal requirements imposed on manufacturers. Howmedica claims that the FDA's labeling requirements for Simplex conflict with a hypothetical adverse judgment on Brooks's state-law failure-to-warn claim. Howmedica raises two distinct arguments in support of this claim, but neither survives careful scrutiny. The majority adds two considerations in favor of

preemption that I find unpersuasive. I address these four arguments in turn.

I

Howmedica professes that it is powerless to alter Simplex's packaging or warning insert, and hence it could not comply both with a state-law judgment and the federal labeling regulations. In effect, while a state-law judgment would require Howmedica to add to its labeling and package insert, it asserts, federal regulations would require Howmedica not to add to its labeling and package insert. Howmedica submits that this Catch-22 epitomizes the need for, and importance of, § 360k preemption.

Howmedica's argument misstates a critical premise. FDA labeling regulations do not mandate that Simplex's label and package insert remain freeze-framed in their 1971-approved state. The FDA's regulations authorize Howmedica to initiate changes to Simplex's labeling. See 21 C.F.R. §§ 814.39(d)(2)(i) (authorizing medical device manufacturers to change labels to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction"), (d)(2)(ii) (permitting "[l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device"). Section 814.39(d)(2) is not a moth-eaten relic of past regulatory efforts to which we attach little or no importance. The provision is a vital component of the FDA's larger regulatory mission of ensuring that manufacturers amend their warnings and their products in response to safety concerns and scientific advancements. The Supreme Court explicitly acknowledged the provision's importance in *Lohr*: "We also note that the agency permits manufacturers of devices that have received PMA to make certain labeling * * * changes which would enhance the safety of the device or the safety in the use of the device without prior FDA approval. See 21 CFR §§ 814.39(d)(1) and (2) (1995)." *Lohr*, 518 U.S. at 497 n. 16 (punctuation removed).

If, for example, Howmedica learns that Simplex poses an unforeseen risk to consumers' health, Howmedica may immediately alter Simplex's labeling and package inserts to warn users of the newly-discovered risk. Howmedica does not have the final say, of course; Howmedica has only the power to initiate review before the FDA concerning the merits of additional warnings. Interim warnings added by a manufacturer must be simultaneously submitted for FDA approval, and the proposed additions will be vetted by FDA doctors. If the FDA approves the additional warnings, the manufacturer may continue to display them. If the FDA rejects the additional warnings, however, the manufacturer must then remove the warnings to maintain compliance with the FDA's specific mandate. In sum, while FDA approval is pending, a manufacturer may include additional warnings on labeling and package inserts.

Section 814.39(d)(2) relieves any tension between Brooks's failure-to-warn claim and the FDA's ongoing oversight of Simplex labeling. Simplex's label and package insert have never contained warnings or information about the risk of contracting asthma. Brooks asserts that the scientific community began to learn of the asthma-inducing propensity of methyl methacrylate vapors in 1985 and 1986, more than a decade after the FDA approved Simplex for use in the United States. Brooks claims that Howmedica negligently failed to warn Simplex users that repeated exposure to vapors released in the mixing process could cause occupational asthma. Though the FDA approved Simplex's labeling without the type of asthma warnings suggested by Brooks, Howmedica could have sought FDA approval to add such warnings in the mid-1980s. Under § 814.39(d)(2), Howmedica could have altered its label or package insert — unilaterally — to alert users to the dangers of contracting asthma, pending permanent FDA approval of those warnings.

Had the FDA refused permission to add asthma warnings, Brooks's failure-to-warn claim would almost certainly be

preempted. In that hypothetical instance, Howmedica would face the dilemma it so fears: a state law judgment would effectively require it to add an asthma warning thatthe FDA mandated must not be included. That hypothetical example is not the present case, however. In this case, Howmedica made no effort to warn Simplex users about asthma, though it had the power to do so initially, and could have done so permanently with the FDA's approval. Brooks's attempt to hold Howmedica liable for this alleged shortcoming in no way conflicts with FDA oversight of medical device labeling generally, or with Simplex's federal labeling requirements specifically.

My understanding of § 814.39(d)(2)'s role in the preemption analysis is identical to that of the former Chief Counsel of the FDA, Richard Cooper. "In some situations, FDA has not, at the relevant time, considered the precise question of whether the insert it had previously approved should be changed in light of subsequent information. Where that is the case, there would seem to be no relevant federal decision entitled to supremacy." Richard Cooper, *Drug Labeling and Products Liability: The Role of the Food and Drug Administration*, 41 FOOD DRUG COSM. L.J. 233, 234-35 (1986) (discussing the regulatory predecessor to § 814.39(d)(2)). Cooper cautions courts not to "over-read" FDA regulations as permitting drug manufacturers carte blanche authority to change labeling or package inserts, *id.* at 235-36, a point with which I fully agree. But Cooper ultimately ascribes to the fundamental point we raise above: manufacturers possess the authority, consistent with § 814.39(d)(2), to initiate the process of changing a medical device label to warn users of a newly-discovered risk. Manufacturers who negligently fail to seek FDA approval for such additional warnings (and to supplement their warnings pending FDA approval) cannot benefit from § 360k's preemption defense because they encounter no conflict between their respective state and federal obligations.

In the present case, Brooks's state law failure-to-warn claim and the FDA's scheme of regulatory oversight may coexist without impediment, and thus preemption is inappropriate.

II

Howmedica also argues there is actual conflict between state and federal requirements — even accepting my interpretation of § 814.39(d)(2) for argument's sake. Howmedica contends the FDA rejected the type of asthma warning that Brooks advocates when it approved Simplex's initial warnings in 1971, and when it oversaw Simplex labeling changes in 1975 and 1976. Howmedica asserts it presented possible warnings to the FDA that encompassed asthma-type risks. The FDA incorporated some of those warnings into the package insert, but rejected others. In either event, Howmedica posits, the FDA's decision to accept or reject such warnings constitutes specific federal regulations inconsistent with Brooks's effort to obtain a state-law judgment requiring an asthma warning.

The record does not substantiate Howmedica's assertions. In the first place, Howmedica has not directed the court to any evidence that warnings specifically pertaining to asthma were discussed by the FDA or presented for its consideration. Howmedica is therefore left to contend that the warnings it did propose, and those considered by the FDA, encompass the same territory as an asthma warning. Howmedica argues, in effect, that some of the warnings it proposed would have "done the work" of an asthma warning, and thus the FDA's rejection of those warnings implies a specific federal prohibition. This contention also lacks any basis for support in the record presented to the district court.

The package insert warnings drafted by the FDA in 1971 during the PMA process mention the following:

> Caution should be exercised during the mixing of [Simplex's] two components to prevent excessive exposure to the concentrated vapors of the monomer which may produce irritation of the respiratory tract, eyes, and possibly the liver.

Brooks App. 202 (Aff. of Christopher Lawler, Exh. K) (Dec. 15, 1998).

It is obvious this warning does not encompass asthma in the manner Howmedica suggests. Warning a Simplex user of possible "irritation of the respiratory tract" is not equivalent to warning the user about contracting asthma through repeated exposure. The warning does not adequately reflect the medical reality of an asthmatic condition. Asthma is a chronic disease that derives from repeated exposure to irritants or allergens, see 1 Gale Encyclopedia of Medicine 347 (1999); Brooks App. 409 (Depo. of Dr. Kaye) (Dec. 16, 1998), yet the Simplex warning bears no mention of duration or long-term exposure. To the contrary, the warning implies to the reader that possible irritation will be only temporary. Moreover, the label does not even hint that such exposure might cause disease.

Howmedica's argument fares no better if the warning in fact connotes permanent harm. Viewed most charitably to Howmedica, the warning's reference to "irritation of the respiratory tract" might incorporate the possibility of long-term suffering. Brooks strongly disagrees any such inference may be drawn, and thus a dispute of material fact (perhaps a dispute of medical fact) would prevent the entry of summary judgment. Because we are presently reviewing the propriety of summary judgment entered against Brooks, we are in no position to draw factual inferences in favor of Howmedica. If such a factual dispute exists, its resolution — and thus the overarching preemption question presented in this case — would require some initial fact-finding. *Cf. Brown* v. *Hotel & Rest. Employees & Bartenders Int'l Union*, 468 U.S. 491,

511 (1984) (expressing an inability to resolve a preemption question until appropriate findings of fact had been made to permit review of the legal question).

Howmedica's assertion that the FDA considered and rejected warnings encompassing asthma in 1975 and 1976 is even less believable. In early 1975, the FDA commenced review of the inhalation toxicity of methyl methacrylate vapors. Howmedica and other manufacturers were required to participate in committee meetings and other proceedings with the FDA. As a result of these discussions, the FDA required Howmedica to alter the Simplex package insert to state Simplex's liquid component was highly flammable and operating rooms should be adequately ventilated. See Brooks App. 126 (Lawler Aff. § 40). The FDA also required Howmedica to send a "Dear Doctor" letter pertaining to concerns of inhalation toxicity. See *id.* at 325-26 (Lawler Aff., Exh. Z).

It cannot fairly be contended that the warnings the FDA required in the mid-1970s were germane to asthma. The FDA was then concerned with the inhalation toxicity of methyl methacrylate vapors. Toxins are essentially poisons. See *supra*, Gale Encyclopedia at 2878. But Brooks does not claim she was poisoned by exposure to Simplex. She claims she contracted asthma from repeated exposure to the vaporous byproducts of the Simplex mixing process. Howmedica has not directed our attention to any evidence that suggests the FDA considered and rejected warnings that would have notified Simplex users of the risk of contracting asthma. The FDA's consideration of inhalation toxicity studies simply does not indicate the FDA considered warnings related to asthma.

And even if the FDA had considered and rejected asthma warnings in the 1970s, Howmedica's counter-argument would still fail. Brooks's failure-to-warn claim is predicated upon scientific discoveries of the mid-1980s. See, *e.g.*, Brooks App. 78 (Plaintiff's Memo. Opp. Summ. J. 21) (Jan.

8, 1998) ("In 1985, scientific literature established a causal relationship between the induction of occupational asthma and exposure to methyl methacrylate, a component of Defendants' bone cement."); *id.* at 465 n. 4 (Expert report of Environmental Health & Safety, Inc.) (July 15, 1998) (citing S. Lozewicz et al., *Occupational Asthma Due to Methyl Methacrylate and Cyanoacrylates*, 40 THORAX 836 (1985)); *id.* at 480. FDA regulations require manufacturers to apprize themselves and the agency of new product risks that come to light subsequent to market approval. Howmedica could have sought FDA approval (under § 814.39(d)(2)) to add asthma warnings when scientists began to notice (or at least thought they began to notice) a causal link between methyl methacrylate vapor exposure and occupational asthma in the mid-1980s. Howmedica could have added such warnings to its package insert immediately, pending final FDA approval or rejection. Howmedica's reference to FDA actions in the 1970s is not responsive to Brooks's assertion that Howmedica failed to warn Simplex users of the risk of contracting asthma when such risks became known in 1985.

Howmedica's argument therefore fails. No evidence in the record demonstrates that current Simplex labeling warns users of the possibility of contracting asthma. Nor does any evidence suggest the FDA considered and rejected other warnings that might have encompassed asthma within their scope. The FDA has not issued Howmedica any specific federal directive pertinent to asthma, and consequently, Howmedica's claim of preemption based upon conflicting state and federal requirements melts away. The majority therefore errs in holding that Brooks's failure-to-warn claim is preempted by federal law.

III

In places, the majority seems to suggest that even if Howmedica's state and federal requirements do not conflict, Brooks's hypothetical state-law judgment nevertheless

"threatens to interfere with a specific federal interest," *ante* at 14 (quoting *Lohr*, 518 U.S. at 500), and thus her state-law claim should be preempted. See *ante* at 19 ("Such 'threaten[ed] interfere[nce]' between specific requirements of state and federal law requires preemption under the MDA.") (quoting *Lohr*, 518 U.S. at 500). I find this suggestion contrary to Lohr and legally untenable in any event.

While predicting that § 360k and its concomitant regulations will occasionally preempt state tort claims, Lohr states "it is impossible to ignore [the regime's] overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. After uttering this broad platitude, the Court got down to the business of deciding when a specific federal interest might be threatened. The ensuing paragraph considers the sort of state and federal requirements imposed on medical device manufacturers. And then, to sum up, the Court concludes "[t]he statute and regulations, therefore, require a careful comparison between the allegedly preempting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.*

The Court's language, and the structure of its discussion, emphasize that while the overarching concern of § 360k preemption is to prevent "threatened interference" with "federal interests," the standard by which to determine such a threat is actual conflict between state and federal requirements. In this case, there is no actual conflict between Howmedica's federal labeling requirements and the requirements imposed by a hypothetical state-law judgment for Brooks — as I have demonstrated above. It would be odd, to say the least, to discard the Court's analytical framework of conflict-motivated preemption in favor of the generic concern present in any preemption case that federal interests persevere.

It is critical to distinguish between the threat to federal interests, to which *Lohr* alludes, and the threat to a particular manufacturer, which *Lohr* does not similarly discuss. The federal interest in MDA cases will rarely if ever be threatened. The FDA always has the last word in labeling decisions. If a manufacturer presents a § 841.39 request to the FDA to add a warning, the FDA's ruling on that request will have preemptive effect. If the FDA refuses permission to add the warning, a subsequent state-law tort claim based on the failure to include that warning will be preempted. The federal interest — the FDA's regulatory mission — is never compromised by a competing state-law judgment because the FDA's decision supplants state tort law.

I acknowledge that manufacturers who are sued in tort before they request additional warnings from the FDA may be threatened. But the federal interest — the subject of discussion in *Lohr* — will not be threatened. Suppose a plaintiff prevails on a state-law failure-to-warn claim against a medical device manufacturer. After judgment is entered, the manufacturer seeks FDA approval to add the warning compelled by the state-law judgment. If the FDA refuses to approve that warning, the manufacturer need not place the warning on its labels because the FDA's requirement preempts the effect of the state-law judgment. In this scenario, the manufacturer may have lost considerable time and money defending the suit, and thus its interests have in some sense been threatened. But the federal interest has not been threatened. When the FDA was presented with a label modification request, the FDA rejected it, and the FDA's judgment carries the day and supplants the state-law judgment for the future based upon § 360k preemption. Section 360k preemption, as envisioned by the Supreme Court, could hardly protect the federal interest more capably.

I therefore resist the majority's apparent attempt to resolve this case based on generic concerns that federal interests might be "threatened."

IV

Finally, spurred on by amicus curiae, the majority makes passing reference to certain policy considerations that militate against a preemption holding in this case. The majority argues that Brooks's effort to add another warning to Simplex's label could result in "over-warning" consumers. The majority also posits that Brooks's lawsuit should not establish medical device labeling policy because she lacks the FDA's capacity to appreciate and balance all the risks presented.

These arguments suggest the FDA's regulations and directives should always supplant state tort suits. Yet the Supreme Court implicitly rejected these policy arguments in *Lohr* by holding at least one plaintiff's state-law failure-to-warn claim was not preempted under § 360k.

Moreover, the majority's considerations form an inappropriate basis for resolving an express preemption case. When Congress has declared its preemptive intent in statutory form, we are limited to interpreting its language in discerning the scope of federal preemption. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) (declaring that the preemptive scope of the Federal Cigarette Labeling and Advertising Act is "governed entirely" by the language in its express preemption provision, 15 U.S.C. § 1334(b)). In the MDA, Congress set forth its intention to preempt some state regulations and requirements placed on medical device manufacturers. Reasonable jurists may debate the meaning of § 360k's words as they apply to particular cases. But we may not rely on broader considerations of public policy, for then we overstep our duty faithfully to interpret the language upon which Congress has agreed.

I respectfully dissent in part, though I do join in Part IV.D of the majority opinion, which concludes that the district court properly granted summary judgment as to Brooks's seeming negligence per se claim.